MTN-003D
An Exploratory Study of Potential Sources of Efficacy Dilution in VOICE Trial

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Presentation Overview

1. Background & Rationale
2. Objectives
3. Population & Sample Size
4. Study Design
5. Data Collection Methods
6. Site burden
7. Timeline
8. Next Steps
Dilution of Efficacy?

FOR IMMEDIATE RELEASE

Microbicide Trials Network Statement on Decision to Discontinue Use of Tenofovir Gel in VOICE, a Major HIV Prevention Study in Women

PITTSBURGH, November 25, 2011 – VOICE, an HIV prevention trial that has been evaluating two antiretroviral (ARV)-based approaches for preventing the sexual transmission of HIV in women – daily use of one of two different ARV tablets or of a vaginal gel – will be dropping the vaginal gel from the study. The decision to discontinue use of the gel, which contains the ARV tenofovir, comes after a routine review of study data concluded that tenofovir gel was not effective in preventing HIV in the women enrolled in the trial.
Sources of Efficacy Dilution

Masse et al., ETE 2009
Adherence

P24_1G. Please rate your ability, over the past 4 weeks, to insert gel exactly as you were instructed.

1. [ ] Very poor
2. [ ] Poor
3. [ ] Fair
4. [ ] Good
5. [ ] Very good
6. [ ] Excellent

We are most interested in knowing on how many days you inserted gel. So if you cannot remember which day(s) exactly you did insert gel, please guess. We prefer that you indicate that you missed some days, even if you cannot remember which exact days you missed.

NOTE: Q25aG repeats going backwards 7 days starting with yesterday.

25aG. Yesterday (x-day) did you insert gel?

1. Yes
2. No
3. Don’t remember
11. In the past 3 months how many times have you had anal sex? By anal sex we mean when a man puts his penis inside your anus.
Primary & Secondary Objectives

- Explore larger contextual issues and specific aspects of the VOICE trial that positively and negatively affected participants’ actual and reported product use.
  - Explore participants’ risk perceptions and motivations to participate in VOICE and the association of these factors with product use or non-use in a prevention trial setting.

- Explore the reasons, motivations and context of engaging in receptive anal intercourse, (and rectal use of gel among VOICE participants in the gel group).
### Population & Sample Size

- Former VOICE participants

<table>
<thead>
<tr>
<th>Study group:</th>
<th>Tablet Users</th>
<th>Gel Users</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td>Reported Anal Sex</td>
<td>4</td>
<td>4</td>
<td>8</td>
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<tr>
<td>Sero-converters</td>
<td>4</td>
<td>4</td>
<td>8</td>
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<tr>
<td>All other women</td>
<td>32</td>
<td>32</td>
<td>64</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>40</strong></td>
<td><strong>40</strong></td>
<td><strong>80</strong></td>
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Sites

- TBD
- Proposed: 3-4 Sites
Study Design

- Exploratory sub-study of VOICE using qualitative in-depth interviews (IDIs)

Be Open, Be free.
Asking the Hard Questions: Adherence

- Discuss motivations/risk perceptions
- Present visual displays/scenarios
  - Different adherence measures
- Role of context on adherence
  - Trial context
  - Social context

What did these responses mean to you?

Excellent
Very Good
Good
Fair
Poor
Very Poor
Asking the Hard Questions: Anal Sex

- Define ‘anal sex’
- Normative statements / scenarios
  - Anal sex behaviors
  - Rectal gel use

...a woman in your community who is participating in an HIV trial like VOICE. She has a partner who doesn’t like to wait until she finishes menstruating to have sex...
Anticipated site burden

VOICE site responsibility

- **Preparatory**
  - IRB submission

- **Study Implementation**
  - Re-contact, and refer participants
  - Possible limited infrastructure support (e.g. clinic space)

- **Post-study**
  - Archive participant files

Not VOICE site responsibility

- **Preparatory**
  - Full responsibility for development of protocol, SSP, SOP, data collection instruments

- **Study implementation**
  - Informed Consent
  - Conduct IDIs
  - Transcribe and translate
  - Manage data entry/ QC

- **Post-study**
  - Data analysis and dissemination
## Estimated Timeline: 2012-2013

<table>
<thead>
<tr>
<th>Activity</th>
<th>Feb</th>
<th>Mar</th>
<th>Apr</th>
<th>May</th>
<th>Jun</th>
<th>Jul</th>
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<td>Collection Tools and Regulatory Approvals</td>
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<td>Data Collection &amp; Management</td>
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<td>Preparation and Dissemination of Study Results</td>
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- Estimated timeline: March 2012 to May 2013
- Table indicates months for specific activities.
Next Steps

- Finalize protocol
- Select chair(s) and site(s)
- Initiate study
Any Questions?